

FEB 12 2002

K013872 1/2

RÜSCH.
INTERNATIONAL
Group Regulatory Affairs
A Subsidiary of Teleflex Incorporated (USA)

Tall Pines Park
Jaffrey, NH 03452
(603) 532-7706
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510(k) Summary

1. Submitter Name, Address, and Date of Submission:

Rick Lykins
Senior Regulatory Affairs Associate
Rüsch International
Tall Pines Park
Jaffrey, NH 03452

Telephone: (603) 532-7706 x 204
Fax: (603) 532-6179
E-Mail: rlykins@tfx.com

Contact: Same as above

2. Name of the Device, Common, Proprietary (if known), and Classification:

Classification Name: Laparoscope, General and Plastic Surgery

Common Name: Extraction Bag

Proprietary Name: Rüsch Memory Bag

3. Identification of the legally marketed device to which the submitter claims equivalence:

The Rüsch Memory Bag is substantially equivalent in design and materials to:

- The MTP Extraction Bag - K990912
- The Cook LapSac - K910914

4. Description of the Device:

The Rüschi Memory Bag will be offered in two (2) sizes - 200ml bag with a 5cm opening for use with a 10mm trocar and an 800ml bag with a 10cm opening for use with a 10mm or 12mm trocar. The 10mm and 12mm application 800ml bags will each have separate and appropriately sized sheaths for insertion into the trocar. Each device consists of a polyurethane bag with a Nitinol wire, a polyethylene pusher and a polyethylene sheath.

5. Intended Use of the Device:

The Rüschi Memory Bag is intended to be used for tissue extraction during laparoscopic procedures including cholecystectomy, appendectomy, nephrectomy, laparoscopic colon surgery, thoracoscopy, lymphadenectomy, tubal pregnancy, intestinal resection, oophorectomy, hysterectomy and myomectomy.

6. Summary of Technological Characteristics:

The Rüschi Memory Bag is identical in every way to the MTP Extraction Bag. The following technological characteristics are the same as or equivalent to the predicate Cook Urological LapSac:

Size Range (Rüschi Memory Bag 200ml and 800ml; Cook Urological LapSac 200ml and 750ml), Material (Rüschi Memory Bag Polyurethane and Cook Urological LapSac Nylon w/Polyurethane Coating), Introducer (An integral part of the Rüschi Memory Bag, an accessory with the Cook Urological LapSac)



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 12 2002

Mr. Rick Lykins
Senior Regulatory Affairs Associate
Rusch International
50 Plantation Drive
Tall Pines Park
Jaffrey, New Hampshire 03452

Re: K013872
Trade Name: Rusch Memory Bag
Regulation Number: 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: GCJ
Dated: November 20, 2001
Received: November 21, 2001

Dear Mr. Lykins:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

Miriam C. Provost
for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K013872

Device Name: Rüsç Memory Bag

Indications for Use:

The Rüsç Memory Bag is intended to be used for tissue extraction during laparoscopic procedures including cholecystectomy, appendectomy, nephrectomy, laparoscopic colon surgery, thoracoscopy, lymphadenectomy, tubal pregnancy, intestinal resection, oophorectomy, hysterectomy and myomectomy.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE) _____

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K013872